UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
SAVANNAH

SHAUNTE DAVIS and **ROBERT DAVIS,**	)	CV414-024
Plaintiffs,	)	Civil Action No.: _____
v.	)	
BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	**COMPLAINT WITH JURY DEMAND**
Defendant.	)	

Plaintiffs Shaunte Davis and Robert Davis ("Plaintiffs"), by and through the undersigned attorneys, hereby bring this cause of action for personal injuries suffered as a proximate result of Plaintiff Shaunte Davis properly using the defective and unreasonably dangerous product Mirena® (levonorgestrel-releasing intrauterine system). At all times relevant hereto, Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendant Bayer Healthcare Pharmaceuticals, Inc. ("Bayer").

PARTIES AND CITIZENSHIP

1. At all relevant times hereto, Plaintiffs Shaunte Davis and Robert Davis were residents of Missouri.

2. Defendant Bayer Healthcare Pharmaceuticals Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Defendant Bayer Healthcare Pharmaceuticals, Inc., can be served with process through its registered agent for service of process in Georgia, Corporation Service Company, 40 Technology Parkway South, Norcross, GA 30092.

3. Defendant Bayer Healthcare Pharmaceuticals, Inc. ("Bayer") was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

4. Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

5. Defendant Bayer is the holder of the approved New Drug Application (NDA) for contraceptive device Mirena®.

6. Bayer is in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women's healthcare products, including the intrauterine contraceptive system, Mirena®.

7. Bayer does business in California through the sale of Mirena® and other prescription drugs in the state.

8. At all times relevant, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena®.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has its principal places of business in states other than the state in which the named Plaintiffs reside.

10. This Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.

12. Plaintiffs aver that the federal judicial district in which Plaintiff's Mirena was inserted was Oklahoma; and the federal judicial district in which Plaintiff's Mirena was surgically removed was Oklahoma. The Plaintiffs request that the law of State of Oklahoma be treated as governing law for purposes of

choice of law analysis. Plaintiffs further request that the Court apply the substantive law of Oklahoma to liability determinations unrelated to punitive damages.

FACTS

13. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

14. Mirena® is an intrauterine system that is inserted by a healthcare provider during an office visit. Mirena® is a T-shaped polyethylene frame with a steroid reservoir that releases 20 μg/day of levonorgestrel, a prescription medication used as a contraceptive.

15. The federal Food and Drug Administration (FDA) approved Defendants' New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. It has been used by more than 15 million women worldwide.

16. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendants admit "[i]t is not known exactly how Mirena works," but provide that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

17. The Mirena® intrauterine system ("IUS") is designed to be placed within seven (7) days of the first day of menstruation and is approved to remain in the uterus for up to five (5) years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

18. The package labeling recommends that Mirena® be used in women who have had at least one child.

19. Mirena®'s label does not sufficiently warn about embedment of the IUS and complications thereof.

20. Defendant has a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

21. In or around December 2009, Defendant was contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) regarding a consumer-directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private setting by a representative from "Mom Central", a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.

22. This Simple Style program represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual

partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena®' s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

23. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

24. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage is a woman becomes pregnant on Mirena®.

25. Finally, Defendant falsely claimed that Defendant's product required no compliance with a monthly routine.

26. Plaintiff Shaunte Davis is currently 35 years old.

27. Plaintiff Shaunte Davis had the Mirena® IUS inserted on February 13, 2007 by Dr. Robert Behrmann at the Reynolds Army Hospital in Fort Sill, Oklahoma without complication according to the manufacturer's instructions.

28. After several months, Plaintiff Shaunte Davis began experiencing abdominal pain and was examined by Dr. Rezaei Abolghasem at the Family Medicine Clinic in Lawton, Oklahoma on May 21, 2007. Dr. Abolghasem was unable to locate the Mirena string after several attempts.

29. On May 22, 2007, x-rays were taken of Plaintiff Shaunte Davis' abdomen which revealed the Mirena overlying the lower half of the sacrum.

30. On September 26, 2007, Dr. Gregory Joslin at the Comanche County Memorial Hospital in Lawton, Oklahoma removed the Mirena device in Plaintiff Shaunte Davis via laparoscopic surgery.

31. As a result of the migration of the Mirena IUD and the surgery related to its extraction, Plaintiff Shaunte Davis has suffered mental and physical pain and suffering and incurred medical expenses that she otherwise would not have incurred.

FIRST CAUSE OF ACTION

PRODUCT DEFECT IN DESIGN OR FORMULATION

32. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

33. At all times herein mentioned, Defendant manufactured, designed, formulated, produced, created, made, constructed and/or assembled Mirena®, used by Plaintiff Shaunte Davis.

34. Defendant's Mirena® was defective in that at the time Mirena® left the control of Defendant, the foreseeable risks associated with its design or formulation exceeded the benefits associated with that design or formulation.

35. Mirena® was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiff Shaunte Davis.

36. At all times herein mentioned, Mirena® was in a defective condition and unsafe, and Defendant knew, had reason to know, or should have known that said Mirena® was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendant.

37. The nature and magnitude of the risk of harm associated with the design and formulation of Mirena®, including embedment within uterine tissue, is high in light of the intended and reasonably foreseeable use of Mirena® as a reversible form of contraceptive.

38. It is highly unlikely that Mirena® users would be aware of the risks associated with Mirena® through either warnings, general knowledge or otherwise. Plaintiffs were not aware of said risks.

39. The likelihood was high that the design or formulation would cause the harm of embedment, in light of the intended and reasonably foreseeable use of Mirena® as a reversible form of contraceptive.

40. The design or formulation did not conform to any applicable public or private product standard that was in effect when Mirena® left the control of its manufacturer, the Defendant.

41. The design or formulation of Mirena® is more dangerous than a reasonably prudent consumer would expect when used in the intended or reasonable foreseeable manner as a reversible form of contraceptive. It was more dangerous than Plaintiffs expected.

42. The intended or actual utility of Mirena® is not of such benefit to justify the risk of embedment and even infertility.

43. There was both technical and economic feasibility, at the time Mirena® left Defendant's control, of using an alternative design or formulation that would not cause embedment.

44. The defective design or formulation of Mirena® was not caused by an inherent characteristic of the Mirena® which is a generic aspect of all contraceptive medications that cannot be eliminated without substantially compromising Mirena®' usefulness or desirability and which is recognized by the ordinary person. This is demonstrated by numerous safer alternative therapies that are available on the market to prevent contraception, without the harmful side effects that can result from Mirena® use.

45. A practical and technically feasible alternative design or formulation was available that would have prevented the harm for which Plaintiffs suffered.

46. By reason of the foregoing, the Defendant is liable to the Plaintiffs for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective in design and formulation.

SECOND CAUSE OF ACTION

PRODUCT DEFECT DUE TO INADEQUATE WARNING AND/OR INSTRUCTION

47. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

48. Defendant had a duty to warn Plaintiff Shaunte Davis of the risks associated with Mirena®, namely, the risk of embedment in uterine tissue.

49. Defendant knew, or in the exercise or reasonable care, should have known about the risk of embedment.

50. Defendant failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of embedment, in light of the likelihood that their product would cause embedment, for which Plaintiff suffered.

51. Defendant's Mirena® is defective due to inadequate post-marketing warning or instruction.

52. Defendant knew, or in the exercise or reasonable care, should have known, about the risk that its Mirena® causes embedment.

53. Defendant failed to provide post-marketing warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of embedment, in light of the likelihood that the product can embed , for which Plaintiff Shaunte Davis suffered.

54. Defendant's product does not contain a warning or instruction regarding embedment for normal healthy individuals.

55. The risk of embedment is not an open and obvious risk or a risk that is a matter of common knowledge in regards to Mirena®.

56. By reason of the foregoing, the Defendant is liable to the Plaintiffs, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective due to inadequate warning or instruction.

THIRD CAUSE OF ACTION

PUNITIVE DAMAGES

57. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

58. Plaintiff's injury was the result of misconduct of Defendant that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question.

59. Defendant fraudulently and in violation of applicable regulations of the FDA withheld from the FDA information known to be material and relevant to the harm that the Plaintiff suffered or misrepresented to the FDA information of that type.

60. By reason of the foregoing, the Defendant is liable to the Plaintiffs for punitive damages, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective.

FOURTH CAUSE OF ACTION

LOSS OF CONSORTIUM

61. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

62. At all times relevant to this complaint, Plaintiff Robert Davis has been the husband of Plaintiff Shaunte Davis.

63. As a result of the medical conditions developed by his wife and the medical treatment and hospitalization that she has and will endure, Plaintiff Robert Davis:

a. lost a substantial measure of his wife's household services; and

b. lost, and will continue to lose in the future, a substantial measure of his wife's consortium.

64. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Robert Davis suffered injuries.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

JURY DEMAND

A jury trial is requested.

Dated: February 12, 2014.

Respectfully submitted,

s/ Mark A. Tate
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